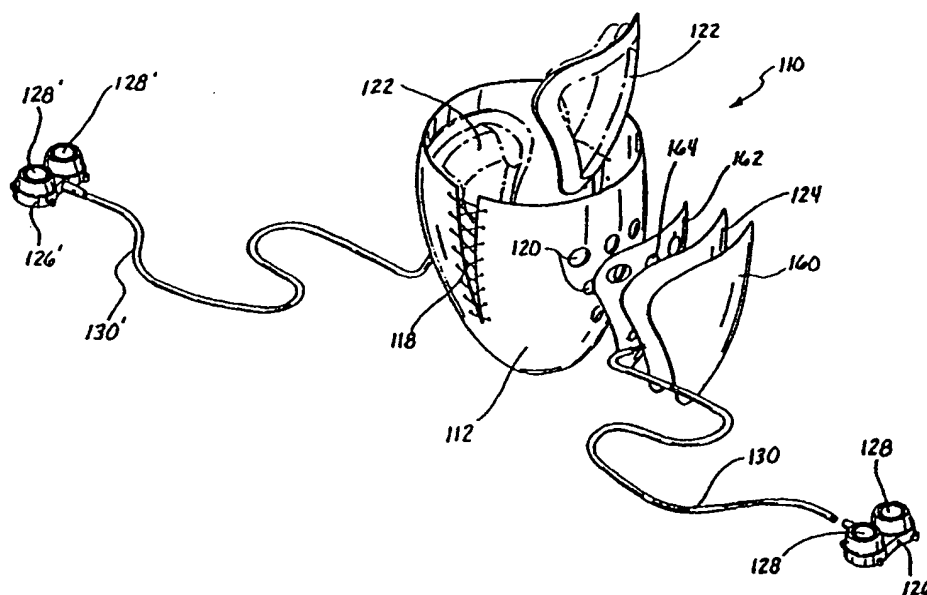




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(71) Applicant: CORSET, INC. [US/US]; 1211 Stradella Road, Los Angeles, CA 90048 (US).			
(72) Inventor: WARDLE, John, L.; 1603 Via Ameno, San Clemente, CA 92672 (US).			
(74) Agents: STOUT, Donald, E. et al.; Stout, Uxa, Buyan & Mullins, LLP, 4 Venture #300, Irvine, CA 92618 (US).		Published Without international search report and to be republished upon receipt of that report.	

(54) Title: METHOD AND APPARATUS FOR REINFORCEMENT OF THE HEART VENTRICLES



(57) Abstract

A unique device is provided for treating heart disorders, and particularly cardiomyopathy. The inventive device is comprised of a compliant containment structure (110) shaped in a configuration such that it surrounds and encases the heart. Within this containment structure are housed two or more inflation pockets (122) that are fabricated from a non-elastic compliant material. These pockets are disposed on the interior surface of the containment structure and are configured to oppose and support the external wall of at least one of the ventricles of the heart. In the preferred embodiment, there are a plurality of relatively small, spaced inflation pockets disposed to act against each ventricle which is to be contained.

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**METHOD AND APPARATUS FOR REINFORCEMENT
OF THE HEART VENTRICLES**

This application claims the benefit of U.S. Provisional Application Serial No. 60/113,232, filed December 21, 1998, which is commonly owned and the contents of which are expressly incorporated herein by reference.

Field of the Invention

The present invention relates to devices and methods for treating cardiomyopathy, a chronic disorder of the heart muscle, and more particularly to an implantable ventricular restraint device which is adapted to confine and control ventricular diastolic expansion.

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Background of the Invention

Cardiac dilation occurs with various diseases of the heart, including heart failure. In some instances, such as ischemic heart disease, the dilation may be localized to only a portion of the heart. On the other hand, cardiomyopathy usually results in global impairment. In the case of hypertrophic cardiomyopathy, there is typically increased resistance to filling of the left ventricle with accompanying dilation of the left atria. In dilated cardiomyopathy, the dilation is typically of the left ventricle with resultant failure of the heart as a pump. As the ventricles become enlarged, the situation is worsened by the resultant leakage which develops around the valvular structures. A sharply reduced ejection fraction is the hallmark of this condition.

Dynamic cardiomyoplasty is one treatment currently being used to treat cardiomyopathy. One current approach being used to treat this disorder is a procedure that involves wrapping and attaching a portion of a patient's own latissimus dorsi muscle around the heart, as described, for example, in the article

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Reverse Remodeling from Cardiomyoplasty in Human Heart Failure,
Circulation, May 1, 1995, Vol. 91, No. 9 (Kass et al.). A pacemaker-like
electrical stimulator is then attached to both the heart and the wrapped muscle.
After a healing period, the wrapped muscle is electrically stimulated in synchrony
5 with the heart which causes the muscle to contract at the appropriate time. This
action actively squeezes the ventricles of the heart, to augment their function. A
reversal of the heart's chronic dilated condition has been found to result in many
cases, and current medical opinion is that patients with chronic heart failure may
be cured of symptoms by providing assistance to ventricular function using this
10 or similar methods. Some have also considered the benefits of merely wrapping
or constraining the heart with skeletal muscle without providing active systolic
assist. In any event, it will be appreciated that, although this method of treatment
has proven effective, it is an open surgical procedure, which involves both
removal of the patient's latissimus dorsi muscle and reattachment of the same to
15 the heart. The frequency of the electrical stimulation, if employed, is the only
adjustment that a medical professional can make to optimize the treatment for
individual patients using this technique.

Another approach which has been considered to address this disorder is
disclosed in U.S. Patent No. 5,702,343 to Alfemess. This patent discloses a
20 device comprising a jacket of biocompatible material, which is applied to and
adjusted to fit the epicardial surface of the heart. The device, once placed,
controls cardiac expansion to a predetermined size. In one embodiment, an
inflatable member is provided which is mounted between the jacket and the
epicardium for selectively adjusting the size of the jacket as the heart remodels
25 and reduces in size responsive to treatment, but there is no disclosed or suggested
provision for regulating the size of the device without surgical intervention. In
many cases, by the time it becomes evident that the patient is in need of treatment
for cardiomyopathy, the dilation has already occurred and the patient is in chronic
disorder. If the constraining device cannot be effectively and easily resized as the
30 heart begins to remodel, it may not continue to be effective, and the possibility

for a maximum remodeling of the heart may be reduced. Another drawback to the disclosed approach of Aiferness is that the disclosed device applies a uniform force to both right and left ventricles. Typically, the left ventricle is the one that causes the disorder as it operates at much higher pressures. This design does not provide the medical professional with any means to accurately optimize or monitor the device's therapeutic effect. The optimal operating parameters for the device may vary dramatically from patient to patient, and these parameters can again change over time as the patient's heart becomes accustomed to the device or goes through a remodeling phase. There is typically a very small imbalance in operating forces that causes the problem and therefore a very small force is sometimes all that is required to correct the condition. Consequently, in the event that the patient were to have an adverse reaction to the device's preset configuration, an urgent surgical intervention would need to be performed to remedy the problem.

What is needed, therefore, is an improved ventricular reinforcement device which may be conveniently re-sized without surgical intervention as the heart remodels to its normal size, and which is capable of independently applying selectively differing forces against the right and left ventricles of the diseased heart.

Summary of the Invention

The present invention addresses the problems outlined above by providing a unique device for treating heart disorders, and particularly cardiomyopathy, comprised of a compliant containment structure shaped in a configuration such that it surrounds and encases the heart. Within this containment structure are housed two or more inflation pockets that are fabricated from a non-elastic compliant material. These pockets are disposed on the interior surface of the containment structure and are configured to oppose and support the external wall of at least one of the ventricles of the heart. In the preferred embodiment, there are a plurality of relatively small, spaced inflation

pockets disposed to act against each ventricle which is to be contained.

On the external surface of the containment structure, or spaced therefrom, there is disposed a recoil balloon, which is configured from an elastomeric material. The containment structure physically separates the inflation pockets
5 from their associated recoil balloon(s). However, a fluid flow path is provided between the pockets and their associated balloon(s). Each recoil balloon has an inflation delivery tube which is in turn fluidly connected to a fluid access port which delivers fluid to the device as needed.

The invention, together with additional features and advantages thereof,
10 may best be understood by reference to the following description taken in conjunction with the accompanying illustrative drawing.

Brief Description of the Drawing

15 Fig. 1 is a schematic, perspective view of a first embodiment of the present invention;

Fig. 2 is a schematic exploded view of the embodiment illustrated in Fig. 1;

Fig. 2a is a schematic exploded view similar to that of Fig. 2, illustrating a somewhat modified version of the embodiment illustrated in Fig. 1;

20 Fig. 3 is a schematic perspective view of a second embodiment of the present invention;

Fig. 4 is a schematic exploded view of the embodiment illustrated in Fig. 3;

Fig. 5 is a cross-sectional view of a portion of the device illustrated in Figs. 1 and 2, wherein the inflation pocket which forms a part of the invention is in an
25 inflated state;

Fig. 6 is a cross-sectional view similar to Fig. 5, illustrating a portion of the device shown in Figs. 1 and 2, during the fluid exchange phase;

Fig. 7 is a cross-sectional view similar to Fig. 6, illustrating a portion of the device shown in Figs. 3 and 4, wherein the inflation pocket and secondary
30 recoil balloon are in a filled state;

Fig. 8 is a cross-sectional view similar to Fig. 7, illustrating a portion of the device shown in Figs. 3 and 4, during the fluid exchange phase;

Fig. 9 is a perspective view of the containment structure which forms a part of the inventive device;

5 Figs. 10A and 10B are plan views, in isolation, of the inflation pockets which form a part of the inventive device;

Fig. 11 is a plan view, in isolation, of the recoil plate which forms a part of the second configuration of the inventive device illustrated in Figs. 3 and 4;

10 Fig. 12 is a schematic view illustrating the placement of the fluid access port which forms a part of the present invention;

Fig. 13 is a schematic view illustrating yet a third embodiment of the inventive device;

Fig. 14 is a perspective view illustrating a fourth preferred embodiment of the invention;

15 Fig. 14a is a perspective view illustrating a modified version of the fourth embodiment shown in Fig. 14;

Fig. 14b is a cross-sectional view of a portion of the embodiment illustrated in Fig. 14a;

20 Fig. 15 is a front elevational view showing the embodiment of Fig. 14 after it has been placed about a heart, with a bypass graft in place;

Fig. 16 is a cross-sectional view of the embodiment illustrated in Fig. 14, showing in detail the inflation pockets of the invention;

25 Fig. 17 is a conceptual graphical plot of the cyclical pressure measured by an external pressure monitor for the device illustrated in Fig. 14 when it is installed on a heart and working full time (i.e. in contact with the heart full time);

30 Fig. 18 is a conceptual graphical plot similar to that of Fig. 17 of the cyclical pressure measured by an external pressure monitor for the device illustrated in Fig. 14 when it is installed on a heart but not in contact with the external surface of the heart full time (i.e. it needs to be re-sized by addition of fluid); and

Fig. 19 is a schematic view illustrating a system for monitoring pressure and/or providing counter-pulsating assist for any one of the embodiments illustrated in Figs. 1-18.

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Description of the Preferred Embodiment

Referring now more particularly to the drawings, there is shown in Figs. 1, 2, 5, and 6 a first embodiment of a cardiac reinforcement device 10 of the present invention which comprises a frame or containment structure 12 preferably formed of a high strength biocompatible mesh-like material, such as polyester fully or partially encased or embedded within a flexible biocompatible material such as silicon or polyurethane, preferably using an injection process. The high strength mesh serves three primary purposes. First, it provides a strong, flexible non-elastic support for the containment structure. Second, it serves as a tear-resistant material which can be sutured to the heart muscle easily. Third, it is lightweight, and provide bypass graft access, as will be described more fully hereinbelow. The advantage of silicon, in particular, is that it has a long history of biocompatibility and provides a good surface to which other items may be attached. Of course, other suitable biocompatible materials, such as polyurethane, may be selected as well, as long as the resultant structure is compliant, but not elastic. It is also within the scope of the invention to employ an alternative configuration involving a polymer frame construction as opposed to the described mesh construction.

The encasing elastomer for the frame or containment structure 12 may be transparent so that a practitioner can see and avoid suturing the device 10 too close to blood vessels. In this first embodiment, the containment structure 12 includes one or more slits 14 along which a series of holes 16 may be provided. Using a biocompatible lace 18, such as polyester, the slits may be laced up as illustrated in Fig. 1, for example, to optimize the size of the frame 12 for variously sized hearts.

It should be noted that, for example, as an alternative to lacing up the slits 14, VELCRO hook and loop fastening straps 18a, 18b may be provided along each side of the slit. This alternative is illustrated in Fig. 2a. During the placement of the device, the VELCRO straps 18a are overlapped to provide an accurate fit, then sutures 19 are made through the VELCRO overlap to secure the sizing permanently.

Port holes 20 are preferably provided in the frame 12 to provide a fluid flow path and permit the exchange of fluid from a plurality of inflation pockets 22 (Fig. 1) to a recoil balloon 24. The inflation pockets 22 (in this embodiment two are provided) are preferably formed of a composite structure made from a high strength biocompatible mesh-like material such as polyester fully encased within a flexible biocompatible material such as silicon or polyurethane (this may be the same material from which the frame or containment structure 12 is fabricated). These components essentially comprise balloons which are flexible and compliant with very low elasticity. Their purpose is to support the outer wall of the heart ventricle. Very low elasticity is desirable because in use there is a requirement that fluid contained within the inflation pockets 22 be expelled through the frame 12 when the pockets 22 are compressed. Consequently, a volume change due to volumetric expansion would be undesirable, as it would compromise the fit of the device on the heart. Preferably, the two provided inflation pockets 22 are of different configurations, and are asymmetrically located, due to the fact that the respective ventricles which they support are different in both configuration and location, with the left ventricle being much larger than the right ventricle. It should be noted that it is within the scope of the invention to provide more than two inflation pockets 22 if desired, since configurations wherein more than one pocket 22 supports a single ventricle may be potentially beneficial in certain instances. Such an embodiment, presently preferred, is illustrated in Figs. 14-16.

The recoil balloon 24 is preferably fabricated of a thin high elasticity biocompatible material such as silicon or polyurethane. This component

comprises a balloon which may be joined to the exterior surface of the frame or containment structure 12 over the port holes 20, as shown particularly in Fig. 2.

5 In the preferred embodiments, a fluid access port 26 is implanted under the patient's skin 27 (Fig. 12) for providing access through which fluid can be delivered to two different device locations. It is preferably constructed of a variety of biocompatible materials, including titanium, polysulfone, polyurethane, and silicon. Similar ports are known in the prior art for use as vascular access ports which are implanted in patients for long-term infusion of medications. The port 26 comprises a plurality of elastomeric septums 28 which can be punctured and accessed frequently with a hypodermic needle (not shown). The septum material properties are such that they self-seal upon removal of the needle.

10 A fluid line 30 conveys fluid, comprising saline or other suitable fluid, which may include both liquids and gases, from the fluid access port 26 to the recoil balloons 2 on either side of the frame 12 (only one balloon 24 is shown in Figs. 1 and 2, but in the first embodiment there is preferably one recoil balloon associated with each inflation pocket 22). The fluid line traverses the patient's muscle 32, adjacent to the bone 34 (Fig. 12), and preferably comprises dual lumen tubing made from a biocompatible material such as silicon or polyurethane. A bifurcation 36 occurs at the distal end of the fluid line 30, and two separate tubes 38 and 40, each communicating with one of the two lumen (not shown), carry fluid to their corresponding recoil balloons. Of course, each of the lumen also corresponds to one of the two elastomeric septa 28 illustrated for this embodiment, so that the result is an ability to separately control the fluid conveyed to each recoil balloon 24.

25 A second embodiment is illustrated in Figs. 3, 4, 7, and 8 (Figs. 9-12 are common to both embodiments), wherein like elements to those in the first embodiment are denoted by like reference numerals, increased by 100. The primary difference between this embodiment and the embodiment of Fig. 1 is the provision of a second recoil balloon 160 (Fig. 4) which "piggy-backs" directly over the first recoil balloon 124. A second set of recoil balloons 160 is preferably

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provided on the opposing side of the frame 112 for operation with the second inflation pocket 122 (not shown). A pressure isolator plate 162, having a plurality of port holes 164, is disposed between the frame 112 and the inner recoil balloon 124. The pressure isolator plate, or recoil plate 162, is preferably made of a rigid plastic material. Additionally, a second fluid access port 126' is provided, having two septa 128' and a fluid line 130'. The fluid access port 126 is arranged to supply fluid to the two recoil balloons 124 and 160 disposed on one side of the frame 112, splitting at the bifurcation 136 (Fig. 3) so that the tube 138 from one lumen supplies the recoil balloon 124, and the tube 140 from the other lumen supplies the recoil balloon 160. Similarly, the fluid access port 126' independently supplies the two recoil balloons (not shown) disposed on the other side of the frame 112. Thus, the practitioner may independently and selectively supply differing quantities of fluid to each of the two recoil balloons disposed in a set on each side of the frame 112, and also independently supply fluid to each set of recoil balloons. In other words, all of the recoil balloons, whether in the same set or in different sets, are isolated from one another, and may be independently pressurized.

The second recoil balloon 160 may be comprised of the same material as the first recoil balloon, or it may alternatively have different material properties. A second fluid chamber 166 (Fig. 6) is provided between the first and second recoil balloons.

The pressure isolator plate, or recoil plate 162 is utilized only in the second embodiment because when the secondary recoil balloon 160 is partially inflated, it puts a compressive load on the inner recoil balloon 124, which in turn compresses the frame wall causing increased pressure on the inflation pocket 122. The purpose of the plate 162 is to isolate those forces.

In yet a third embodiment of the invention, the system may be constructed as shown in either the first or second embodiments. The only change is that, as illustrated in Fig. 13, in this embodiment the fluid access port 26, 126, 126' is augmented by a pressurized fluid reservoir system 280 having a one-way valve

281, such as a duckbill valve, for example. With this configuration, rather than manually adding fluid, fluid from the reservoir 280 may be automatically added to each of the inflation pockets 22, 122 if and when the pressure in the inflation pockets drops below a predetermined value. Preferably, in this embodiment, the fluid reservoir system 280 comprises a biasing device, such as a constant force spring 283, a fluid reservoir 284, and a seal 284a disposed between the fluid reservoir 284 and the spring 283. In operation, the spring 283 moves back as fluid enters from the fluid access port 26, 126, 126', and moves forward to push fluid out of the device. With this arrangement, the fluid reservoir pressure equals the spring force, which is always maintained as long as fluid is present.

There is shown in Figs. 14-16 a fourth presently preferred embodiment of the invention, wherein like elements to those of the first embodiment are designated by like reference numerals, increased by 300. Elements which are the same as in prior embodiments, having similar structure and function, may not be again described. Thus, a cardiac reinforcement device 310 constructed in accordance with this embodiment comprises a containment structure 312 which is preferably fabricated entirely of a high strength biocompatible mesh-like material, such as polyester. This construction, as compared to the mesh and frame construction disclosed in connection with the prior embodiments, provides a benefit of a lighter weight structure with less bulk, and therefore greater compliance, which minimizes the impairment of cardiac function. It also improves visibility, and provides ready access for a bypass graft, as will be discussed infra. As in the prior embodiments, there are provided a plurality of port holes 320 in the structure 312, but they are preferably greater in number and distributed about the entire circumference of the structure 312, as illustrated.

It should be noted that the mesh construction for this preferred embodiment may be constructed with a square pattern, if desired, and could resemble a hair net in appearance.

Unlike the prior disclosed embodiments, this embodiment is particularly suited to the accommodation of one or more existing bypass grafts 384 (Fig. 15)

which may be present on the patient's heart 385. A device constructed as illustrated in the first three embodiments may not be as suited to this type of condition, because the inflation pocket may cover and compress the bypass vessel, causing a restriction in the blood flow. In addition, in severe cases of cardiomyopathy (large dilation of the heart), there may not be sufficient space for the recoil balloons to expand without being compressed against the surrounding anatomy if they are attached to the side of the inventive device, as shown in the embodiments of Figs. 1, 2, and 3. This compression would, of course, affect the pressures at which the device operates.

In contrast, the present embodiment comprises a plurality of multiple small inflation pockets 322, rather than the fewer, larger inflation pockets disclosed in the previous embodiments. The multiple inflation pockets 322 simulate the appearance of bubble wrap, but are spaced apart enough to provide a sufficient clearance between them to accommodate an existing bypass graft 384, or to allow a subsequent bypass graft 384 to be attached. Because the inflation pockets 322 are spaced, and small, no one pocket 322 should cover and compress the bypass vessel sufficiently to cause undesirable blood flow restriction. If, however, that is the case, because of the number of inflation pockets 322, one or more of them can be removed during the installation procedure to accommodate the existing bypass graft 384.

Furthermore, this preferred embodiment overcomes the problems discussed supra, related to the unavailability of sufficient space for the recoil balloons of the prior embodiments in the event of a severely enlarged heart, by reducing the side profile and relocating the recoil balloons away to a location where space is not at a premium. The device otherwise functions in substantially the same manner as in the previous embodiments.

Preferably, when it is necessary to perform a bypass procedure subsequent to installation of the device 310, the bypass graft is routed around the exterior surface of the structure 312. The large number of access holes 320 provided in the mesh material increase the likelihood that the graft can be

attached without removing the device 310. However, in the event that additional access is required, the material comprising the structure 312 is capable of being cut to provide additional access holes without compromising the mechanical integrity of the device. In some instances, it may even be preferably to provide
5 fewer and/or smaller access holes 320, and to just be prepared to cut additional holes during a later bypass procedure, for the purpose of access. In the prior embodiments illustrated in Figs. 1-13, if the device were already implanted and a bypass procedure became necessary, it is highly likely that the device would need to be removed in order to gain access to the artery and make the attachment of the
10 vessel, as the site would likely be substantially covered by one of the inflation pockets. This is a difficult prospect, because of the tendency of the frame or containment structure 12, 112 to embed itself into the surrounding tissue over time. However, in the embodiment of Figs. 14-16, even if one or more inflation pockets 322 are in the way, they can be removed to accommodate the procedure without materially affecting the overall operating effectiveness of the device.
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Preferably, the multiple inflation pockets 322 associated with each ventricle are linked together, in that they are all attached to one of the septums 328 of the fluid access port 326, as illustrated in Fig. 14. The fluid line 330 attached to each of the septums 328, which is preferably of a dual lumen
20 construction, as discussed supra in connection with the prior embodiments, includes at its distal end a plurality of smaller fluid delivery tubes 386, which are each individually fluidly connected to a separate inflation pocket 322 disposed over an associated ventricle. With this advantageous arrangement, the inventive system may be adapted to fill the inflation pockets 322 for a particular ventricle
25 in parallel, or in series, as desired, so that the pockets 322 may be, for example, filled in series from the base to the top of the structure 312 as the associated ventricle expands in a similar manner, or, alternatively, may be filled simultaneously.

In one version of this preferred embodiment, illustrated in Figs. 14, 15,
30 and 16, the recoil balloons 324 are disposed in each fluid line, remote from the

structure 312, rather than being attached to the exterior surface of the frame 312, as in prior embodiments. As in the prior embodiments, the balloons 324 are preferably fabricated of a thin high elasticity biocompatible material such as silicon or polyurethane. This arrangement offers the benefit of reducing the space that the device occupies immediately around the heart, and instead permits the disposition of the balloons 324 elsewhere in the chest cavity where space may not be as restricted. One other advantage of this construction is that the balloons may be changed out by utilization of only a minor surgical procedure, involving only the removal of easily detachable fittings 387 (Fig. 14), such as Luer Locks, in the event that balloons with different pressure capacity or recoil properties would be of benefit.

Another version of this preferred embodiment is illustrated particularly in Figs. 14a and 14b. This embodiment is very similar to that of Fig. 14, except that a double recoil balloon, comprised of a pair of inner and outer recoil balloons 324, 360 is utilized, rather than a single recoil balloon 324. This is similar in concept to the embodiment illustrated in Fig. 4, with back-to-back recoil balloons 124, 160. As shown, the detachable fitting 387 comprises a male Luer Lock 387a and a female Luer Lock 387b. Lumen 330a provides a fluid line for filling the inner balloon 324, while lumen 330b provides a fluid line for filling the exterior balloon 360. A fluid line block 330c forces fluid to enter the outer balloon 360 through an entry port 330d. Passage 387c in the female Luer Lock 387b provides an exit port for fluid exiting the interior recoil balloon 324 for the inflation pockets. In operation, when fluid is injected into the cavity 360a between the exterior balloon and the interior balloon, the exterior balloon 360 becomes distended and causes an increase in the filling pressure for the interior balloon 324. This configuration thus, as is apparent, provides a convenient method for increasing operating pressures, if desired, and thereby perhaps avoiding undue intervention.

Another advantageous feature of the present embodiment is its capability to directly deliver Trans echocardial drugs to the pericardium. In a preferred

configuration, a third elastomeric septum 388 is provided in the fluid access port 326 (Fig. 14), which is attached to a drug delivery line 389. A distal portion 390 of the drug delivery line 389 is arranged to wrap around the exterior surface of the structure 312, as illustrated in Fig. 14, and is provided with a plurality of drug flow holes 391 spaced therealong where the distal portion 390 is in proximity to the pericardium, to ensure the uniform delivery of the drug at its intended site. The drug flow holes 391 may also be used to remove fluid from the pericardium area if this become necessary.

In operation, the device 10, 110, 310 is installed for operation on a patient's heart by first removing or opening up the pericardium (not shown). The frame or containment structure 12, 112, 312 is then placed over the heart with the inflation pockets 22, 122, 322 disposed adjacent to one or both of the ventricles. Using the side slits 14, 114 and laces 18, 118 which are incorporated in the frame 12, 112, or the VELCRO straps which are discussed supra at page 6, line 27 to page 7, line 4, the device can be accurately sized to the heart (the frame 312 is sufficiently elastic, being comprised entirely of flexible mesh material, that no slits are required). This is achieved in a similar manner as one would tighten a shoelace. The frame is then securely sutured to heart muscle to ensure that it cannot migrate from its intended location and also to isolate the forces on the right and left sides of the device during use. The fluid access ports 26, 126, 126', 326 are then attached to the chest just under the patient's skin 27, as illustrated in Fig. 12. Alternatively, with respect to the third embodiment shown in Fig. 13, the pressurized fluid reservoir 280 and one-way valve 282 are appropriately positioned within the patient's thoracic cavity (not shown).

When the device 10, 110, 310 is first placed on the heart, the inflation pockets 22, 122, 322 are empty and completely collapsed. The device is actuated by introducing fluid into the inflation pockets. In the Fig. 12 embodiment, this is accomplished by the employment of a pressure monitoring syringe filled with saline or another suitable fluid. A needle is attached to the syringe and then inserted through the patient's skin 27 and into the septum 28, 128, 128', 328 of

the fluid access port 26, 126, 126', 326 and the fluid is injected. The injected fluid fills the fluid access port, the inflation delivery line 30, 130, 130', 330', flows through the recoil balloons 24, 124, 324, and finally enters the inflation pockets 22, 122, 322. The pressure of the inflation pockets is monitored by a pressure wave, which occurs as the ventricle empties and refills. The fluid level is increased in the pockets until there is always a positive pressure present. This indicates that the inflation pockets 22, 122, 322 are in contact with the ventricle when it is systolic. Figs. 5 and 7 illustrate each of the first and second disclosed embodiments wherein the inflation pockets 22 and 122, respectively, are in their filled state.

In the third embodiment, shown in Fig. 13, pressurized fluid will initially be introduced into the system from the pressurized fluid reservoir 280, through the one-way valve 282, rather than manually via a syringe. In all other respects, operation of the third embodiment is substantially similar to that described above with respect to the first, second, and fourth embodiments, and, in fact, any of the first, second, and fourth embodiments can utilize an automated fluid pressurization system as shown in the third embodiment.

Once the device 10, 110, 310 has been initiated, or activated, it functions by assisting the failing and dilating heart muscle. The device provides a substantially constant external restraining force, which increases as the ventricle goes from a systolic to a diastolic state. As a ventricle is filled, it dilates and compresses its adjacent inflation pockets 22, 122, 322. This, in turn, reduces the volume of the inflation pockets. This is because, in the first two embodiments, the fluid is permitted to escape through the port holes 20, 120 in the frame 12, 112 into the recoil balloon 24, 124 on the external surface of the frame 12, 112, as shown in Figs. 6 and 8, respectively. The fourth embodiment operates a little differently, because the recoil balloons 324 are disposed remotely from the containment structure 312, in the fluid lines 330. In this embodiment, as the fluid pressure increases, the fluid is displaced from the inflation pockets and is permitted to escape in a backwards direction through the fluid tubes 386 into the

fluid line 330, which leads to the recoil balloon 324. As the volume of the inflation pockets decreases, the volume of the recoil balloon increases by an equal amount.

5 In any event, in all of the embodiments, in order for the fluid to enter the recoil balloons, the volume of the recoil balloons must increase. Thus, the wall of the balloons 24, 124, 324 must be forced to stretch and dilate. The force required to dilate these balloons increases as the volume increases, which in turn places a larger restraining force on the heart. Once the ventricle has completely dilated, the process is reversed and the potential energy now stored in the recoil balloons assists in forcing blood from the ventricle during the systolic state.

10 Over the course of time, as the patient responds to the action of the inventive device and the heart shrinks in size, the inflation pockets 22, 122, 322 will no longer be assisting the ventricle through the full operating cycle. This condition can be easily corrected by repeating the set-up procedure and observing the pressure wave. If a reduction of the size of the heart has occurred, the pressure wave will not be constant and, by simply adding additional fluid to the inflation pockets 22, 122, 322 via the fluid access ports 26, 126, 326, the inner boundary size of the device will shrink and it can again be made to assist the heart through its full operating cycle.

20 Again, it should be noted, as discussed supra, that the third embodiment illustrated in Fig. 13 offers a means for accomplishing the foregoing re-sizing process automatically. By using this embodiment, the practitioner can leave the patient for longer durations without making pressure volume adjustments to the inflation pockets 22, 122, 322. In this configuration, fluid is automatically added to the inflation pockets whenever a predetermined pressure low occurs, and is therefore self-adjusting until the reservoir is emptied.

25 The second disclosed embodiment offers a particular benefit in that if the practitioner determines that a patient would benefit from the application of a higher restraining force, such can be done by introducing additional fluid into the second fluid cavity 166 between the first and second recoil balloons, via the

30

additional available fluid access port. Fluid forced into this space 166 will stretch the surface of the balloon 160, as illustrated in Fig. 7, thereby creating a greater resistance to the filling of the inner recoil balloon 124, which in turn increases the restraining force placed upon the heart. This adjustment may be made to any or all recoil balloons, as desired.

A major advantage of this design is that if a patient has an adverse reaction to the restraining forces of the frame 12, 112, 312 immediate relief may be obtained by removing fluid from the inflation pockets via the fluid access ports 26, 126, 126', 326.

It should be noted, as another advantageous feature of the invention, that the inflation pockets disclosed in any of the foregoing embodiments may be coated, if desired, with a drug infused osmosis material. If this is the case, the drug may leach out slowly for a term immediately after placement of the inventive device over a patient's heart, thereby aiding recovery.

Referring now, in particular, to Figs. 17-19, there is illustrated a minimally invasive arrangement for monitoring and accurately measuring diastolic and systolic pressures and performance in an entirely new way. This data can be used for diagnostic purposes, to optimize the adjustment of the device, and/or to monitor therapy. In order to achieve this, the fluid access port 26, 126, 326 of the device 10, 110, 310 is directly attached, via a connecting flow line 492, to an external pressure monitoring system 493 (Fig. 19). This system may comprise a monitor, or a pulsating pump. To create a closed loop, a needle 494 is placed into the elastomeric septum 28, 128, 328, which, in turn, is attached to the connecting flow line 492 using, for example, a Luer lock connector 494a.

Under normal operating conditions, diastolic expansion will cause the pressure inside the device to increase, and systolic contraction will cause the pressure to decrease. This pressure change occurs along the entire fluid path between the device and the pressure monitoring system, so that the monitoring system 493 receives data that translates into a complete pressure wave, as illustrated in Figs. 17 and 18, which each represent generalized plots of pressure change over time.

In Fig. 17, which represents a situation where the device is working full time, the data plots a full pressure SIN wave 495, with a peak diastolic pressure 496 and a minimum systolic pressure 497. On the other hand, as illustrated in Fig. 18, if the device is only in contact with a ventricle for a portion of the cardiac cycle, the pressure only changes while a compressive force between the device and the ventricle is in effect. This results in a partial pressure wave 498, with a flat spot 499 which represents the period of time x during which the device is not in contact with the ventricle, and thus is doing no work. In such an instance, the practitioner, viewing the plot on the monitoring device 493, would recognize the need to add fluid to resize the device to optimize its fit, as described supra, in order to ensure that it is working full time.

Although the inventive device has been disclosed as primarily having utility as a passive heart restraining or constraining device, it is within the scope of this invention to also provide direct active assistance to the heart if cardiac dysfunction occurs. This may happen immediately after installation of the device or at any time thereafter. In this mode of use, the device is used to provide systolic assistance instead of diastolic restraint. In order to achieve this, the fluid access ports of the device are directly attached to an external pump monitoring system 493, as illustrated in Fig. 19, for the purpose of controlling systolic inflation of the inflation pockets 322 by means of counter pressure pulsation. To create a closed loop control between the device and the pump/monitoring system 493, a needle 494 is placed into and attached to each fluid access port, which in turn is attached to an independent flow line 492 which is connected to the pump/monitoring system. Due to the rapid pulse rate required to achieve success with this procedure, it is preferred to use a low inertia medium, such as helium, as the fluid for activating the device 310.

While this invention has been described with respect to various specific examples and embodiments, it is to be understood that the invention is not limited thereto and that it can be variously practiced within the scope of the following claims. For example, while the foregoing embodiments are disclosed

as being adapted for restraining both ventricles of the heart, it is clearly within the scope of this invention to install the device 10, 110, 310 in such a manner that only one ventricle is restrained. Typically, this one ventricle will be the left ventricle, as this is the one which typically causes the cardiomyopathy condition.

WHAT IS CLAIMED IS:

1. A device for treating a heart disorder, comprising:
a first structure for placement over a patient's heart;
a second structure for applying pressure against a first portion of said heart during a portion of the pumping cycle of said heart; and
5 a third structure for applying pressure against a second portion of said heart during a portion of the pumping cycle of said heart;
wherein the pressure applied by said second and third structures may be independently controllable so that the different pressures may be selectively applied against said first and second heart portions.
2. The device as recited in Claim 1, wherein said first structure comprises a containment structure for enclosing a substantial portion of said heart.
3. The device as recited in Claim 1, wherein said second structure comprises a first inflation pocket.
4. The device as recited in Claim 3, wherein said third structure comprises a second inflation pocket disposed in a spaced relationship from said first inflation pocket.
5. The device as recited in Claim 3, and further comprising a recoil balloon disposed outwardly of said inflation pocket and a fluid passage disposed between said inflation pocket and said recoil balloon to permit fluid to be exchanged therebetween.
6. The device as recited in Claim 5, wherein said inflation pocket is filled with fluid, and said first portion of said heart is the left ventricle, wherein when the heart enters a diastolic state, the left ventricle expands against said

inflation pocket, thereby forcing fluid from said inflation pocket through said fluid passage and into said recoil balloon.

7. The device as recited in Claim 6, wherein when said heart enters a systolic state, said fluid returns through said fluid passage from the recoil balloon into the inflation pocket, so that the inflation pocket becomes pressurized and exerts pressure against said left ventricle.

8. The device as recited in Claim 4, and further comprising a fluid injection port for injecting fluid into each of said first and second inflation pockets, wherein differing amounts of fluid may be injected into each of the inflation pockets independently, thereby permitting different pressures to be selectively applied against said first and second heart portions.

9. The device as recited in Claim 8, wherein said fluid injection port comprises two septums disposed just beneath the skin of said patient, each of which is fluidly connected through a separate fluid passage to a corresponding one of said inflation pockets.

10. The device as recited in Claim 8, wherein said fluid injection port comprises a pressurized fluid reservoir and a one-way valve, so that fluid may be automatically injected into each of the first and second inflation pockets independently, responsive to pressure in each pocket.

11. The device as recited in Claim 2, wherein the containment structure is comprised substantially entirely of a flexible, biocompatible open mesh material, having a plurality of access openings disposed therein which are distributed about an outer surface of said containment structure.

12. The device as recited in Claim 3, wherein said first inflation pocket comprises a plurality of relatively small, spaced inflation pockets.
13. A device for treating a heart disorder, comprising:
a first structure for placement over a patient's heart;
a second structure disposed within said first structure for supporting a portion of said heart during at least a period of time when the heart is in a diastolic state;
5 a third structure disposed outside of said first structure which is adapted to operate in conjunction with the second structure to support the heart.
14. The device as recited in Claim 13, wherein said first structure comprises a containment structure for enclosing a substantial portion of said heart.
15. The device as recited in Claim 13, wherein said second structure comprises an inflation pocket comprised of a substantially non-elastic biocompatible material.
16. The device as recited in Claim 14, wherein said third structure comprises a recoil balloon.
17. The device as recited in Claim 16, and further comprising a fluid passage disposed between said inflation pocket and said recoil balloon to permit fluid to be exchanged therebetween.
18. The device as recited in Claim 17, and further comprising a fluid injection port for injecting fluid into said inflation pocket, wherein the amount of fluid being injected into said inflation pocket may be increased responsive to the

size of the heart, in order to ensure that pressure is applied by said inflation pocket against said heart at least when said heart is in a diastolic state.

19. The device as recited in Claim 14, wherein said third structure is spaced from said first structure.

20. The device as recited in Claim 14, and further comprising a drug delivery line for selectively delivering drugs to said heart through said first structure.

21. A device for treating a heart disorder, comprising:
a containment structure adapted for placement over a patient's heart;
a first inflation pocket for applying pressure against the left heart ventricle during at least a period of time when the heart is in a diastolic state;
5 a second inflation pocket for applying pressure against the right heart ventricle during at least a period of time when the heart is in a diastolic state; and
a fluid injection port comprising a fluid line for independently delivering pressurized fluid to each of said first and second inflation pockets, so that
10 different pressures may be selectively applied against each of said left and right heart ventricles.

22. A device for treating a heart disorder, comprising:
a containment structure adapted for placement over a patient's heart;
an inflation pocket disposed within said containment structure for supporting a portion of the heart during at least a period of time when the heart is
5 in a diastolic state; and
a recoil balloon disposed outwardly of said containment structure which is adapted to operate in conjunction with said inflation pocket to support the heart.

23. A method for treating a heart disorder, comprising the steps of:
applying a first level of pressure against a first portion of a patient's heart;
and
applying a second level of pressure against a second portion of said heart.

24. The method as recited in Claim 23, and further comprising the step
of placing a containment structure over said heart.

25. The method as recited in Claim 23, wherein the step of applying a
first level of pressure is accomplished by inflating a first inflation pocket which is
disposed to lie adjacent to said first heart portion within said containment
structure to said first level of pressure.

26. The method as recited in Claim 25, wherein the step of applying a
second level of pressure is accomplished by inflating a second inflation pocket
which is disposed to lie adjacent to said second heart portion within said
containment structure to said second level of pressure.

27. A method for treating a heart disorder, comprising the steps of:
applying a first level of pressure against a first portion of a patient's heart;
monitoring the size of said heart over time; and
increasing said first level of pressure to a second higher level of pressure
5 when a reduction in size of said heart is detected.

28. A device for treating a heart disorder, comprising:
a containment structure for placement over a patient's heart; and
a plurality of inflation pockets for applying pressure against a portion of
said heart during at least a portion of the pumping cycle of said heart.

29. The device as recited in Claim 28, wherein said containment structure has an outer surface and comprises an open mesh material having a plurality of openings distributed about said outer surface, said plurality of openings providing access for visualizing coronary arteries and performing
5 bypass procedures on said heart without removing said device.

30. The device as recited in Claim 28, wherein said plurality of inflation pockets comprise a plurality of inflation pockets which are each substantially smaller than a ventricle of said heart, and which are spaced with respect to one another, said plurality of inflation pockets together having
5 sufficient size and being capable of applying sufficient force to restrain a heart ventricle.

31. The device as recited in Claim 30, and further comprising a fluid injection port and a fluid passage connected between said fluid injection port and each of said plurality of inflation pockets, for injecting fluid into each of said plurality of inflation pockets.

32. The device as recited in Claim 31, and further comprising a recoil balloon which is fluidly connected to each of said plurality of inflation pockets, said recoil balloon receiving fluid from said inflation pockets during a portion of the heart pumping cycle and delivering fluid to said inflation pockets during
5 another portion of the heart pumping cycle.

33. The device as recited in Claim 32, wherein said recoil balloon is disposed at a location remote from said containment structure.

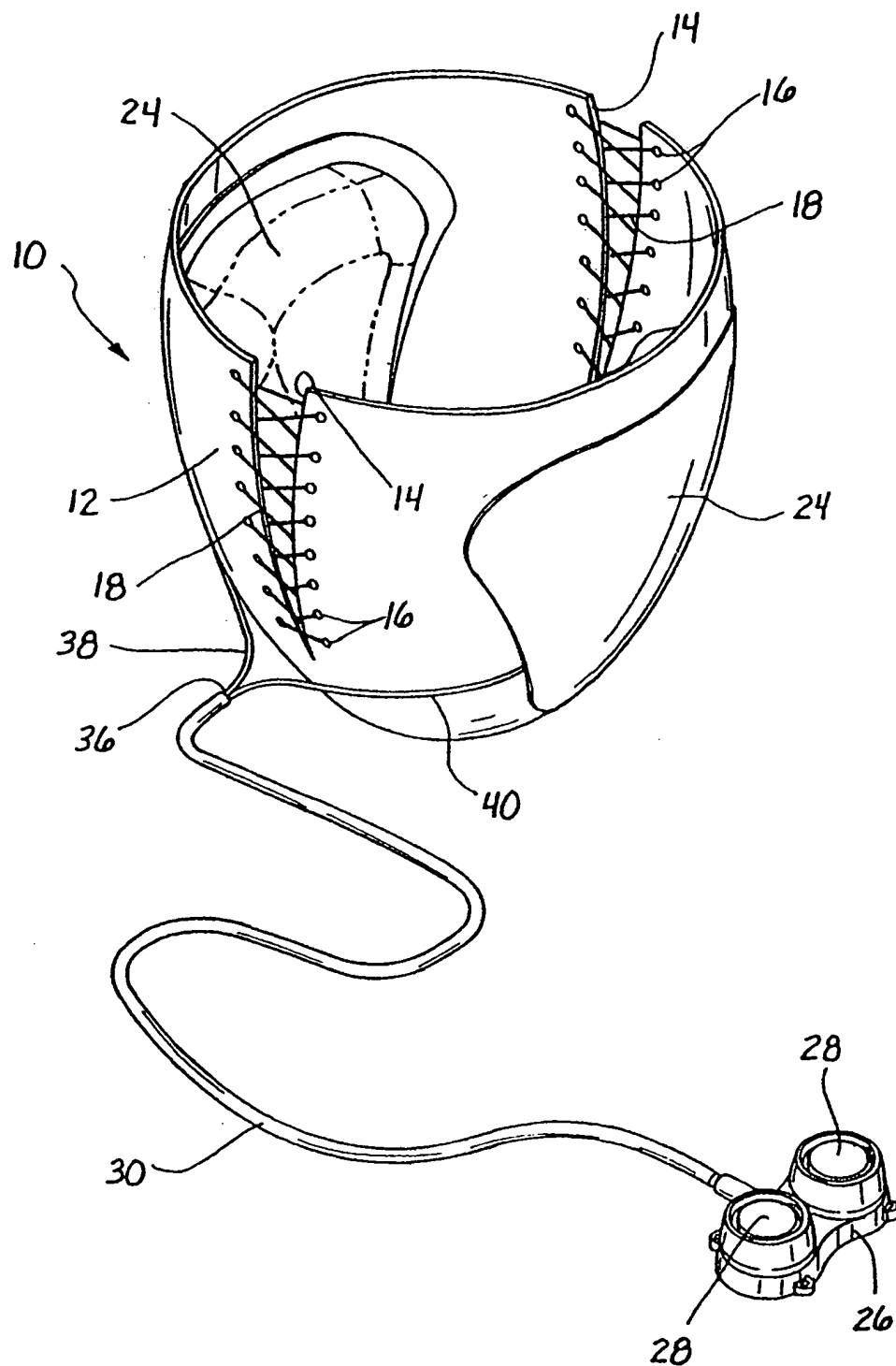
34. The device as recited in Claim 33, wherein said recoil balloon is disposed in said fluid passage, said fluid passage comprising a fluid line, said

recoil balloon being connected to said fluid line using detachable fittings so that it is readily replaceable.

35. A device for treating a heart disorder, comprising:
a containment structure for placement over a patient's heart;
a drug injection port;
a drug delivery line fluidly connected to said drug injection port, said drug
5 delivery line including a distal portion which is disposed about a circumferential
portion of said containment structure; and
a plurality of drug flow holes spaced along said drug delivery line distal
portion, for selectively supplying drugs to said heart.

36. A dual function device for treating a heart disorder, comprising:
a containment structure for placement over a patient's heart;
at least one inflation pocket for applying pressure against a portion of said
heart during at least a portion of the pumping cycle of said heart;
5 a fluid injection port; and
a fluid passage connected between said fluid injection port and said at
least one inflation pocket;
said device being operable to inject fluid into said at least one inflation
pocket during any portion of the pumping cycle of the heart, so that it may
10 operate either passively to restrain the size of the heart during the diastolic
portion of the pumping cycle, or actively to provide a rapid pressure pulse to
assist the heart during the systolic portion of the pumping cycle.

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*Fig. 1*

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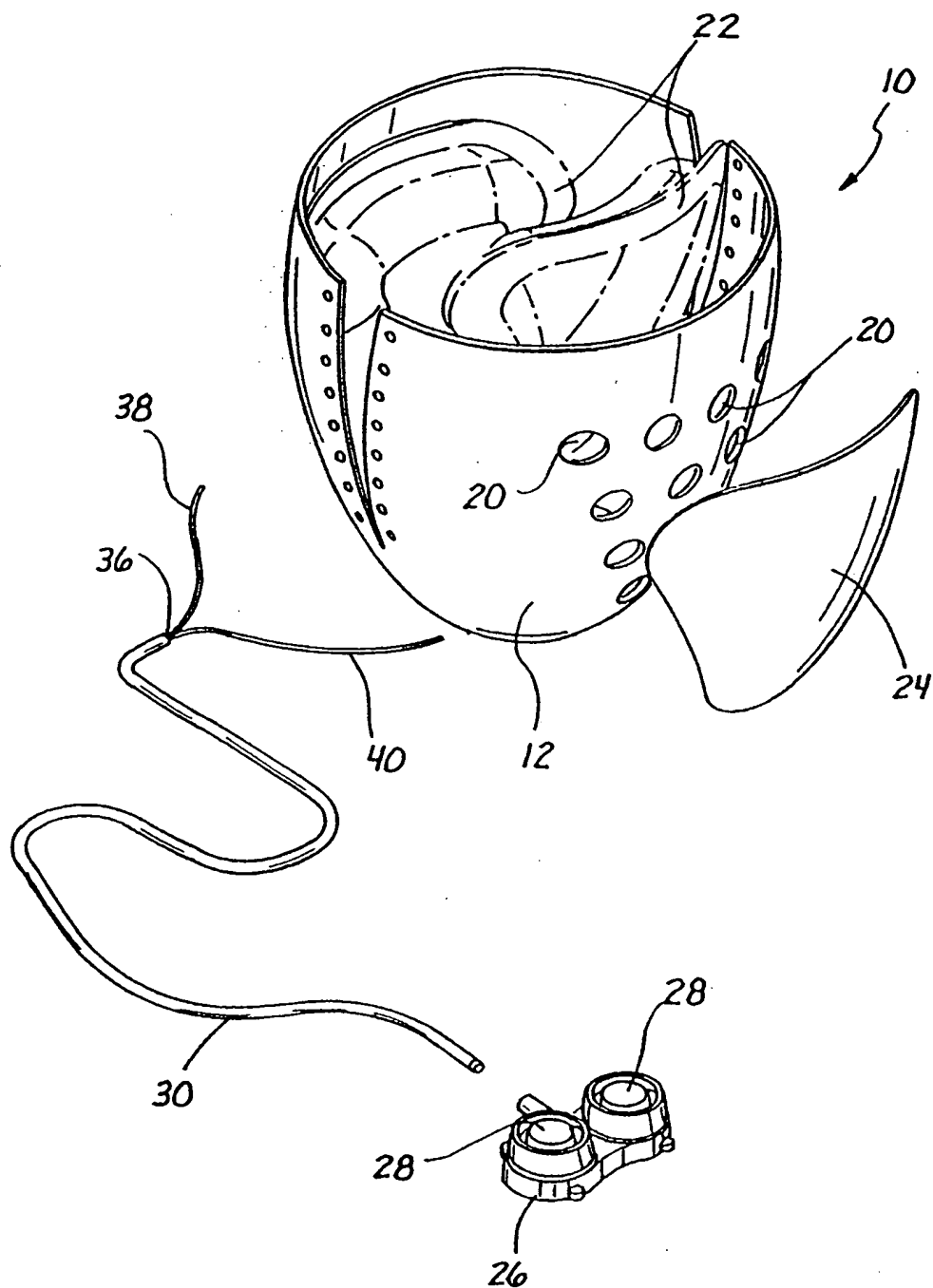
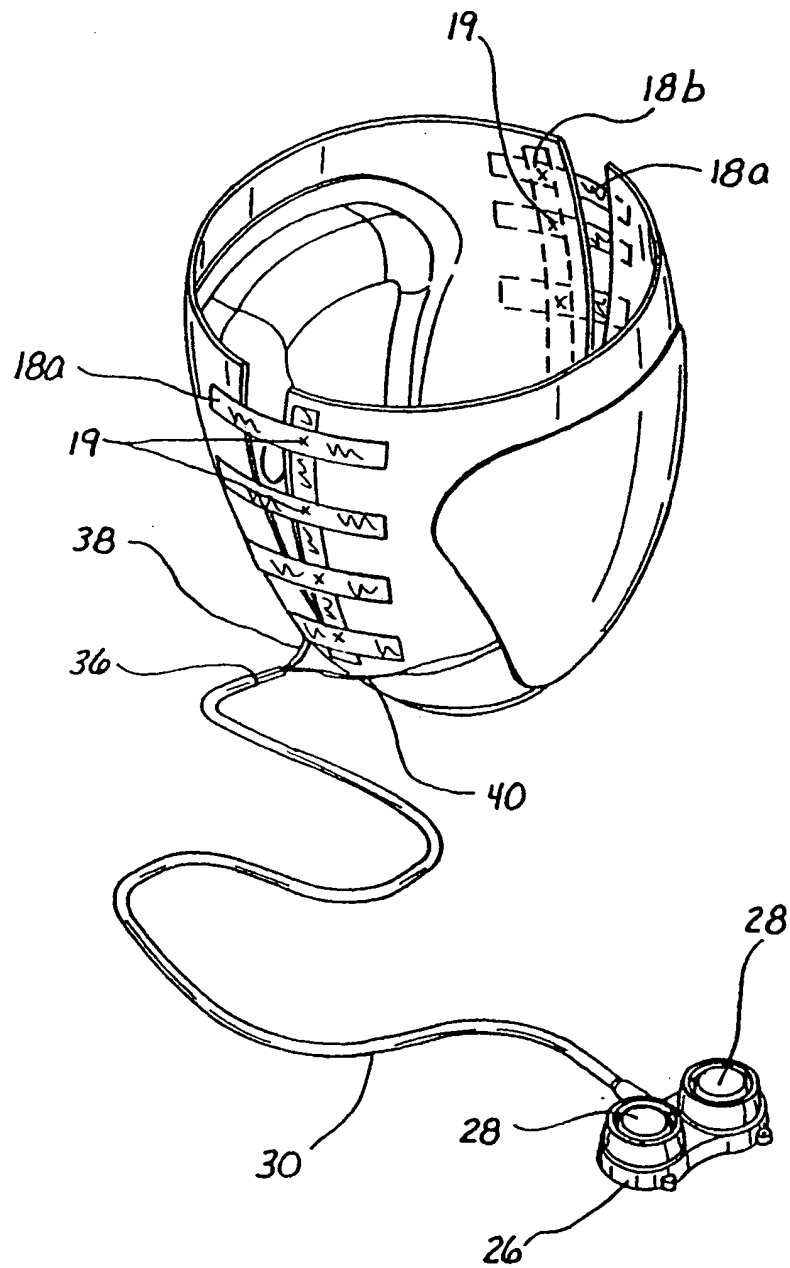


Fig. 2

*Fig. 2a*

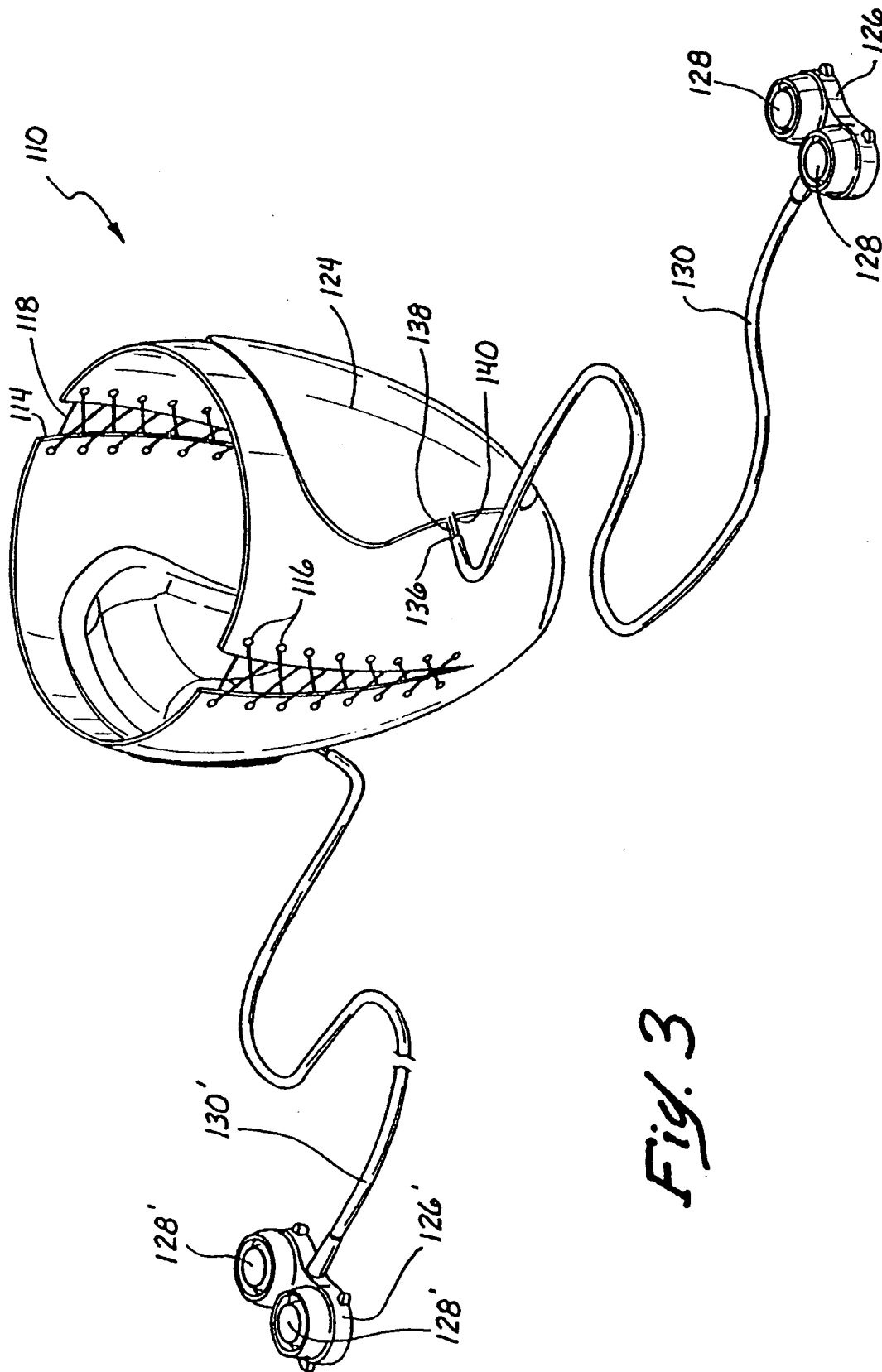


Fig. 3

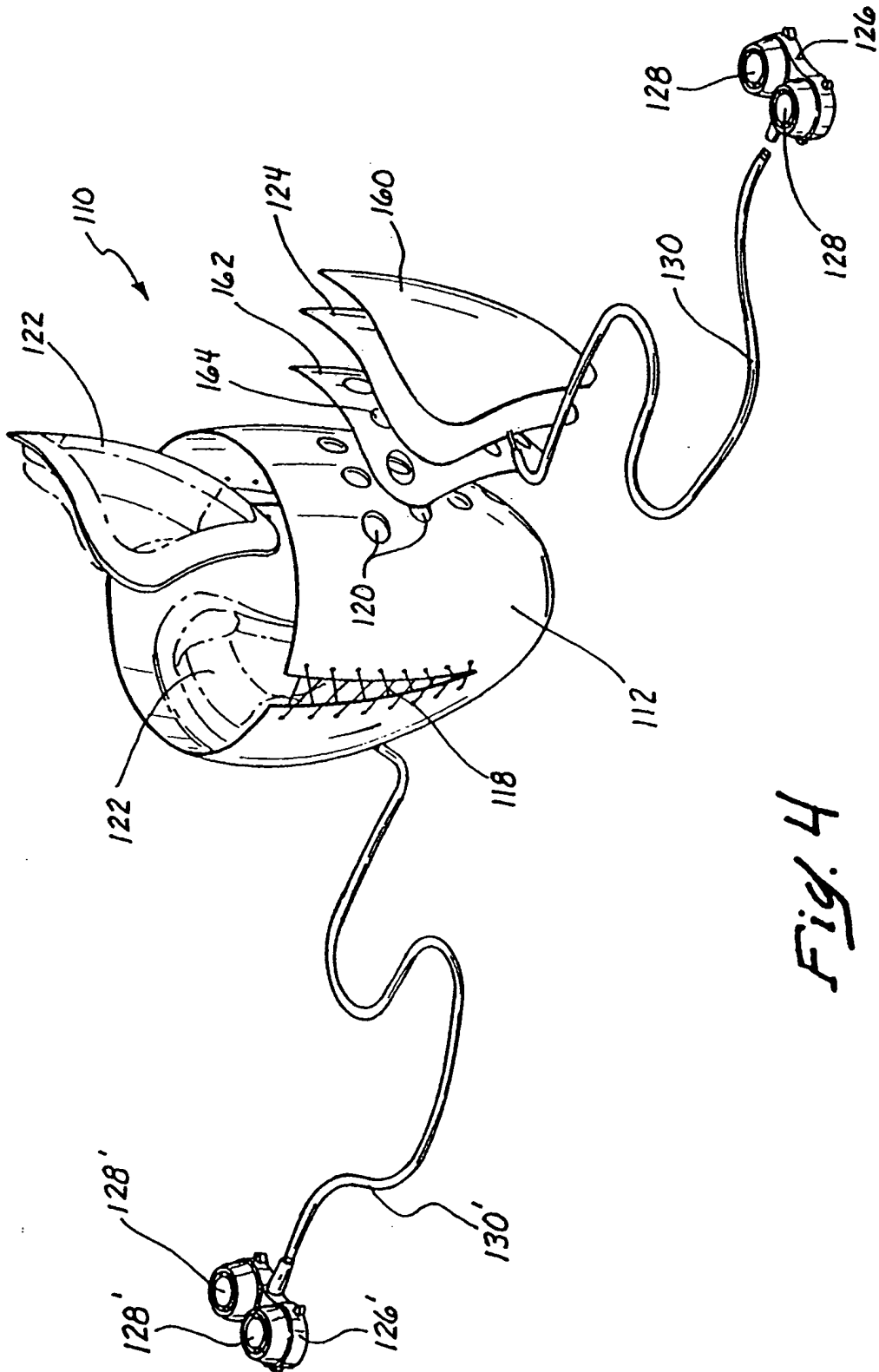


Fig. 4

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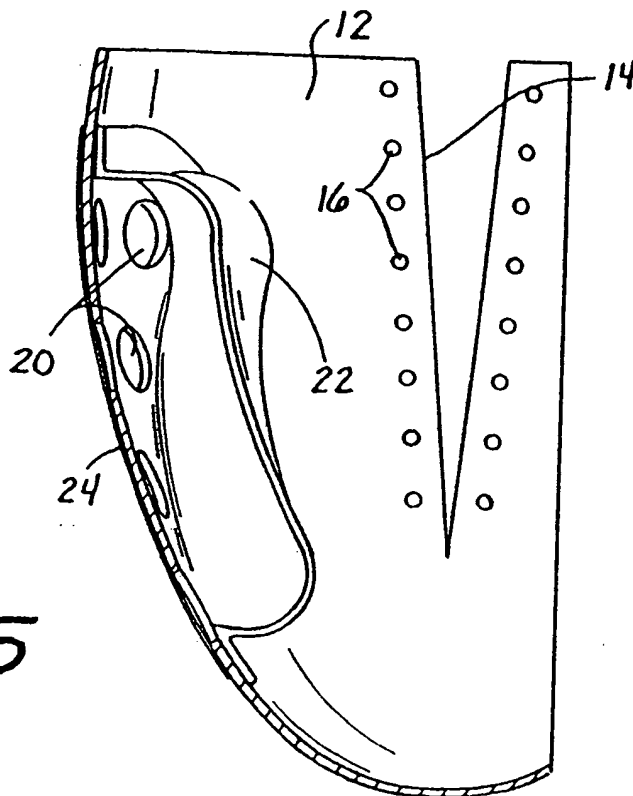


Fig. 5

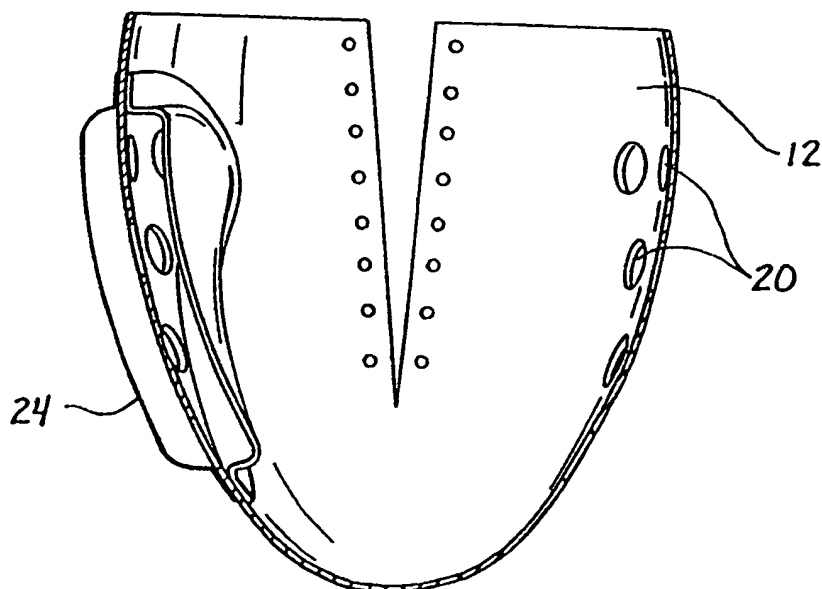


Fig. 6

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Fig. 7

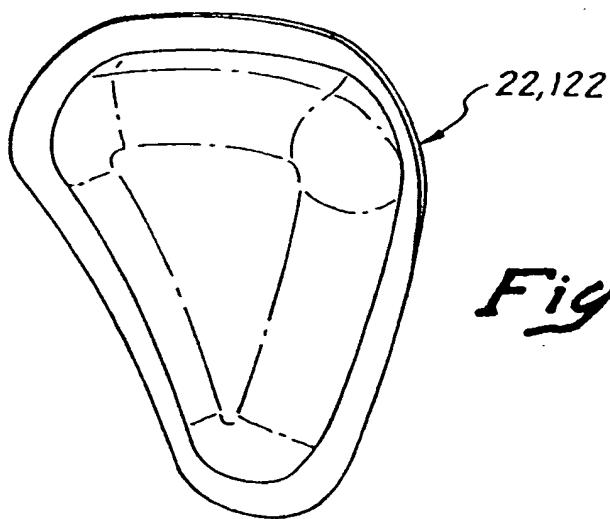
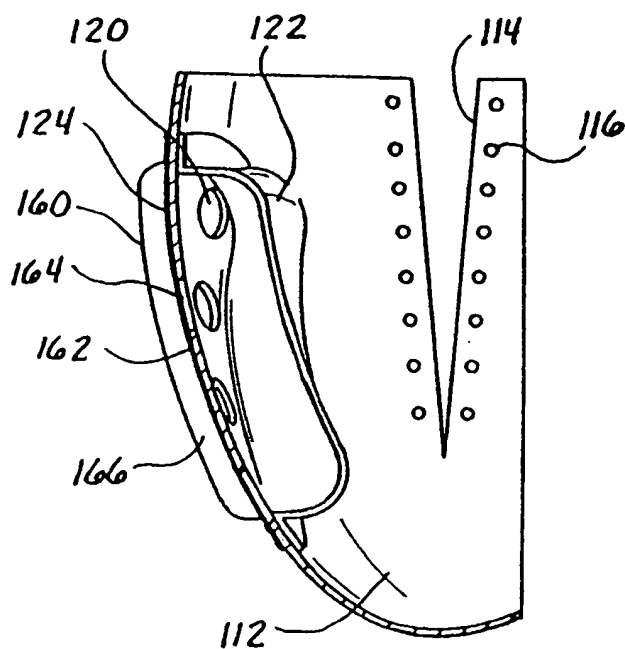
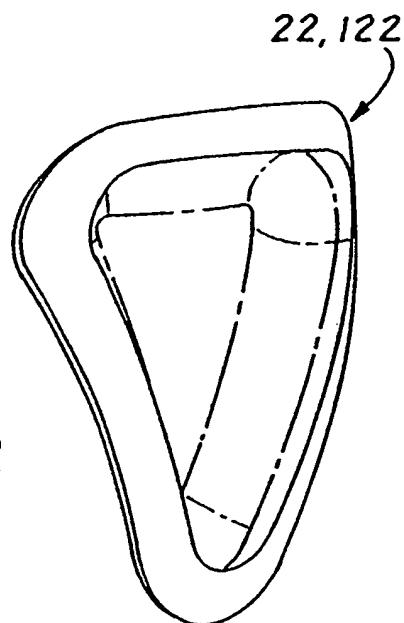


Fig. 10A

Fig. 10B



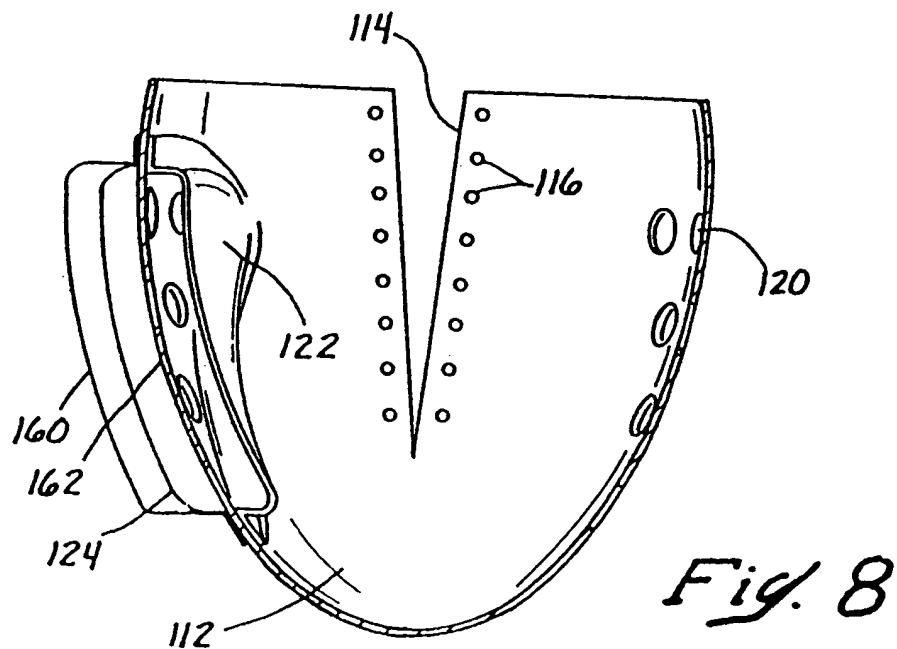
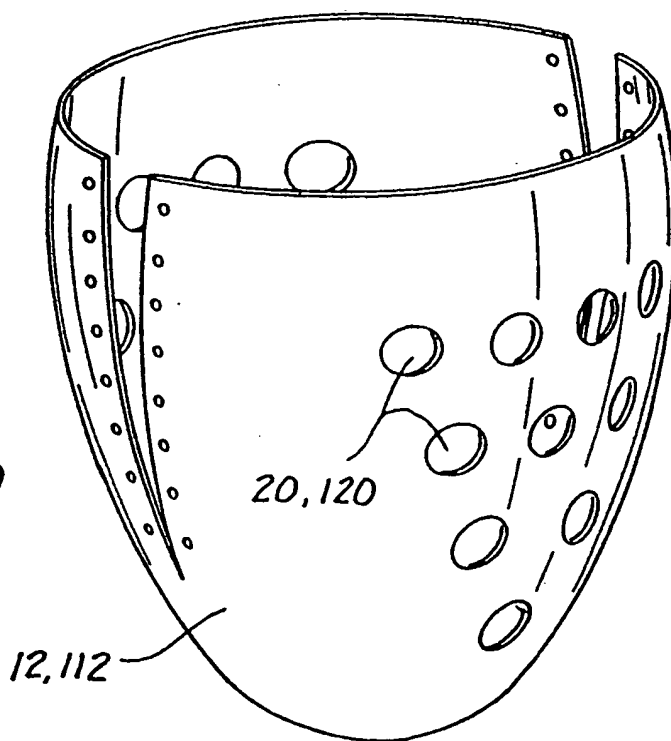


Fig. 9



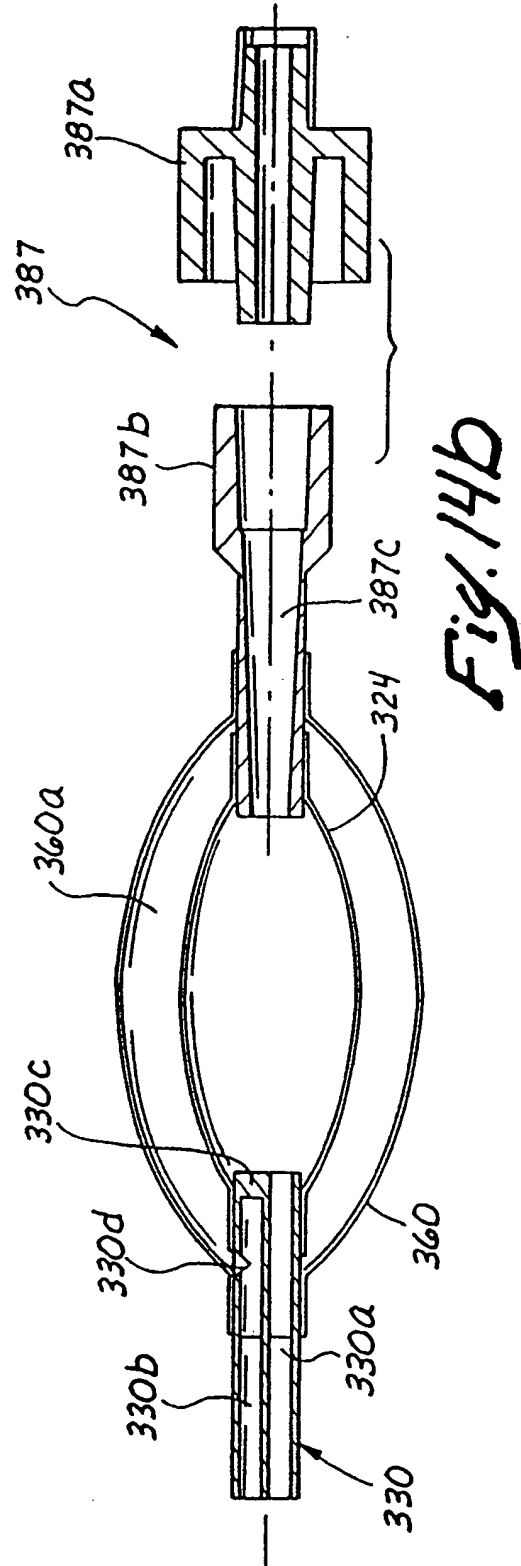
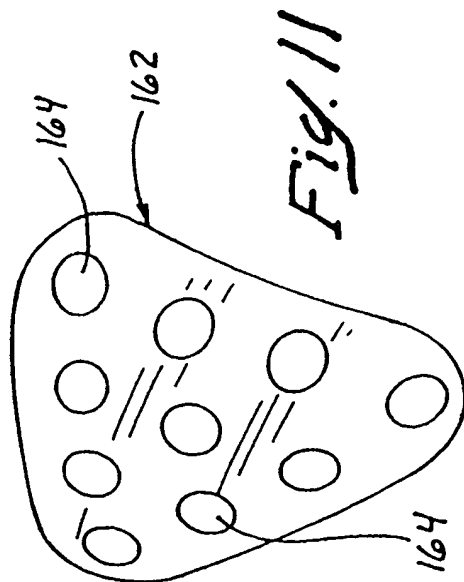
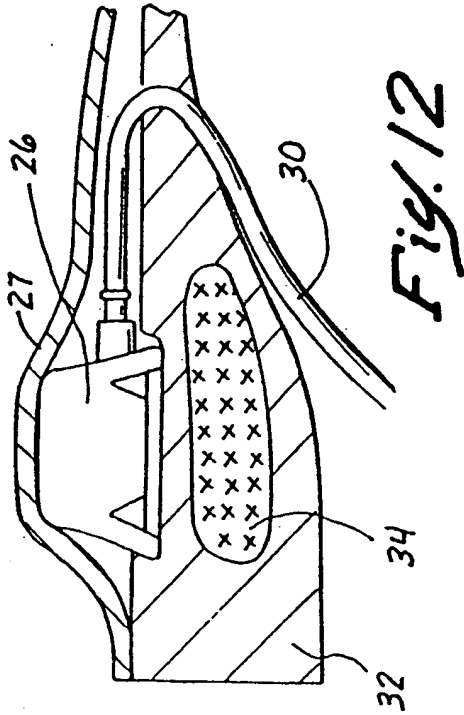
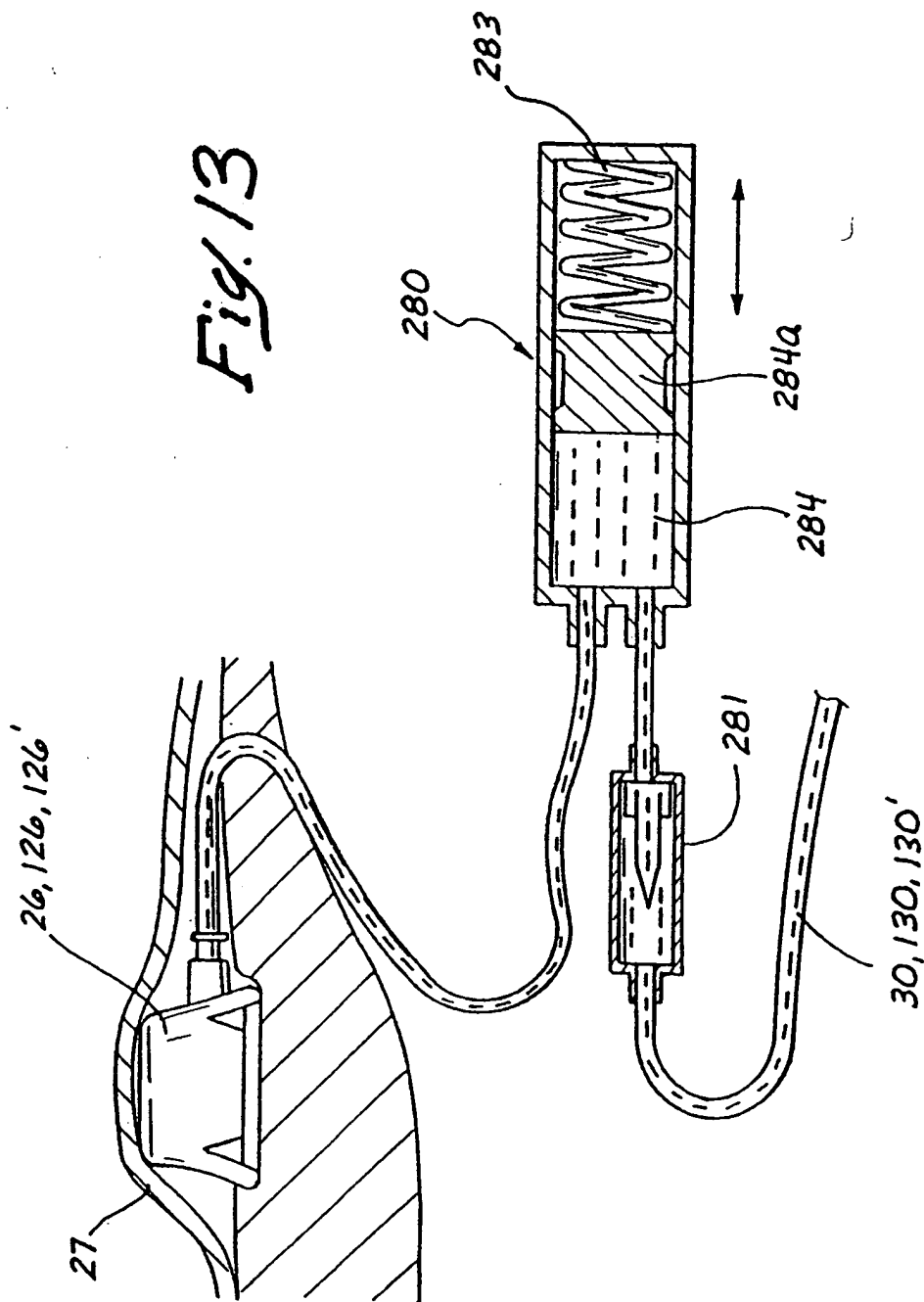


Fig. 13



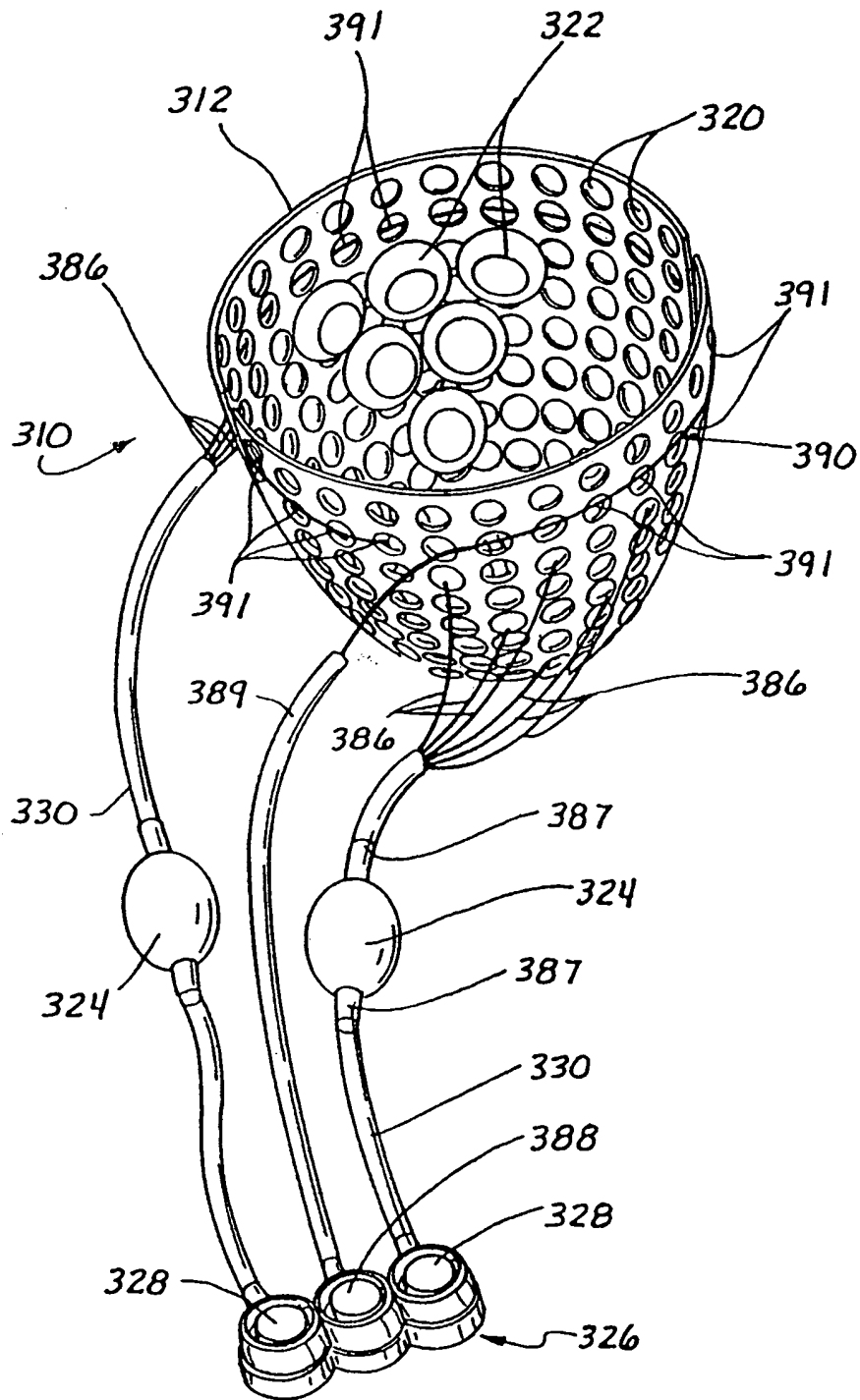
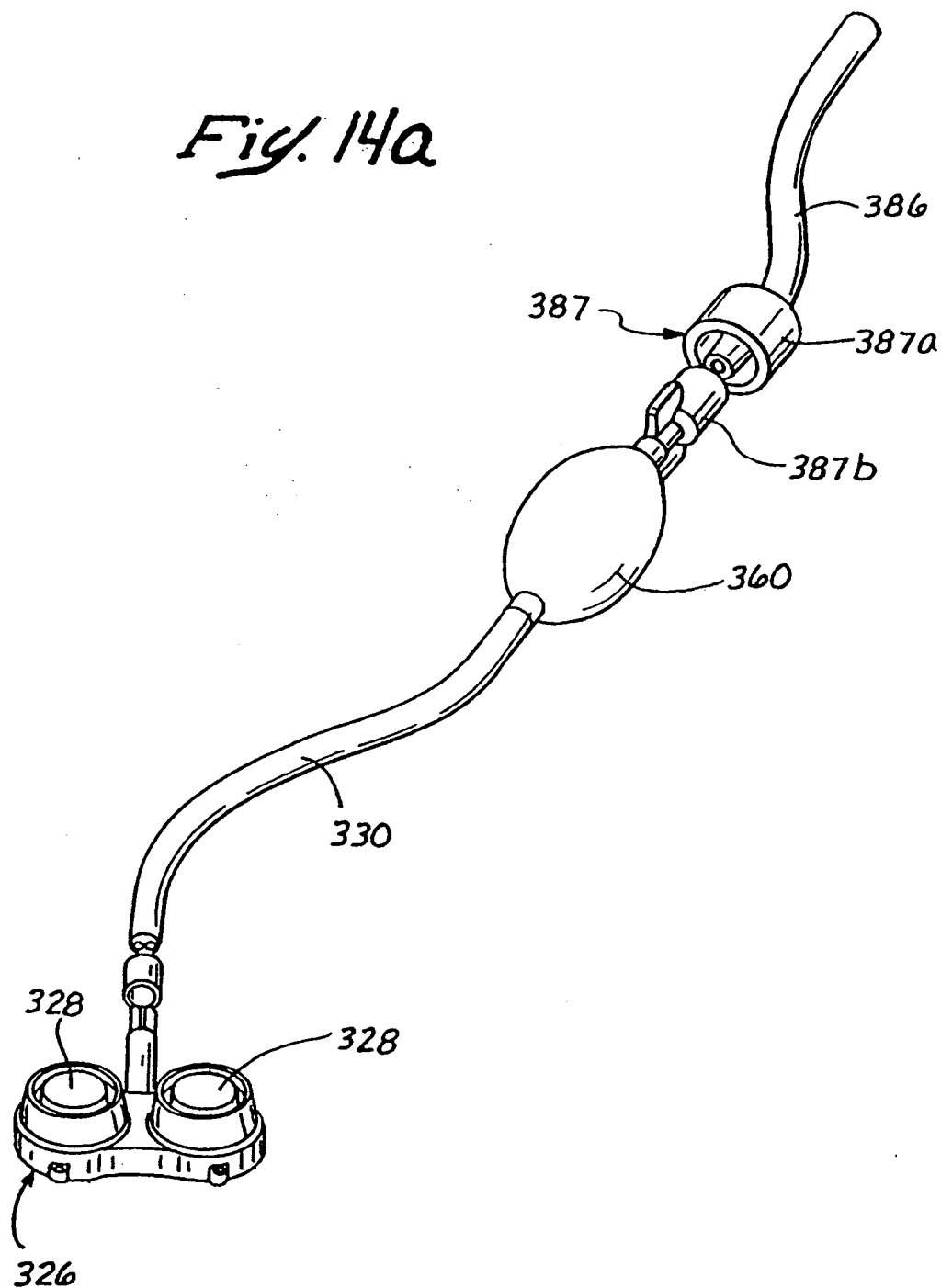


Fig. 14

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Fig. 14a



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Fig. 15

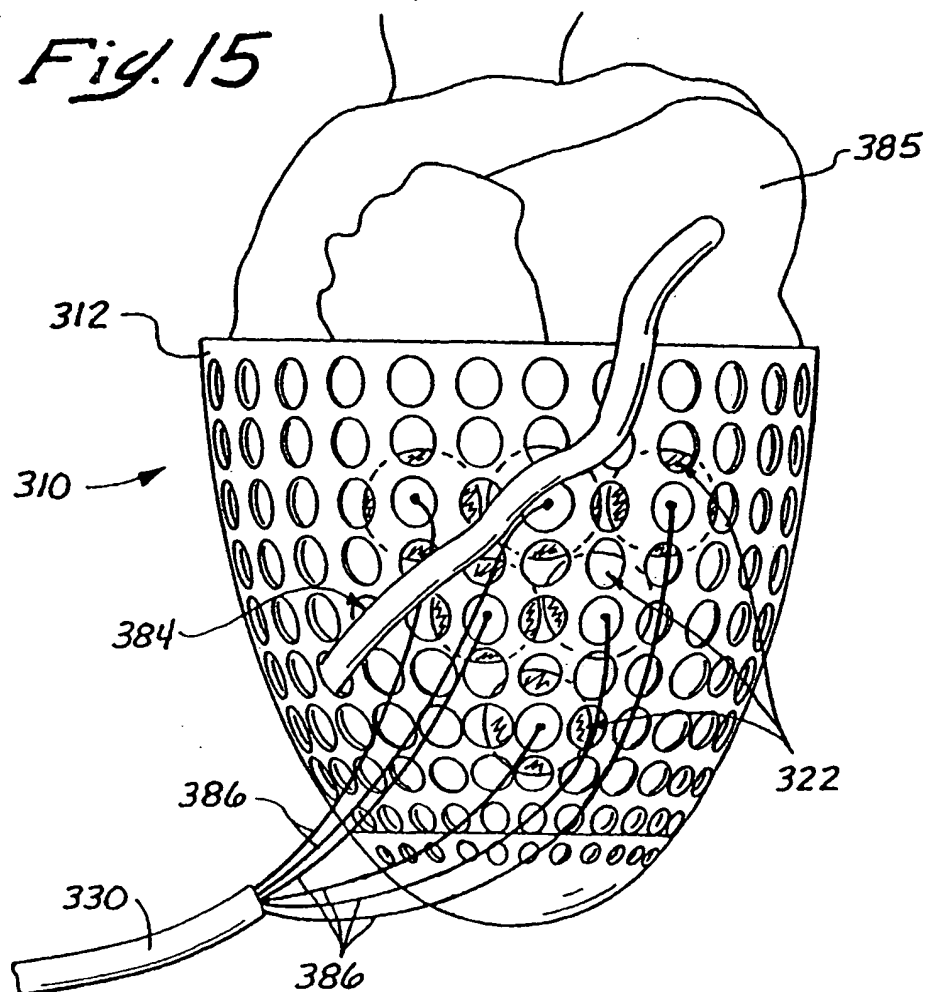
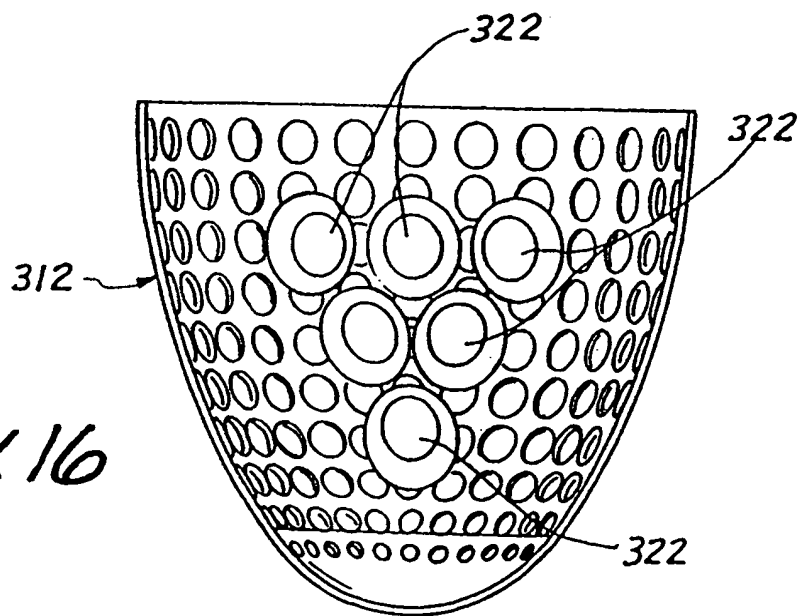


Fig. 16



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PRESSURE
CHANGE

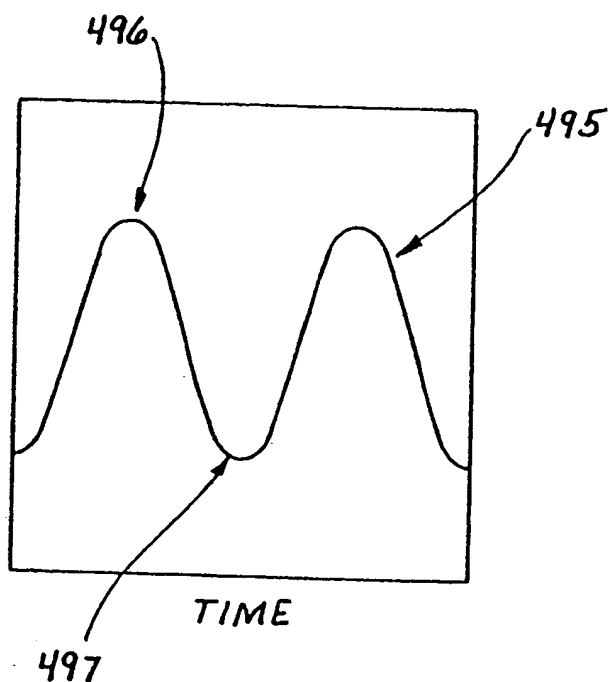


Fig. 17

PRESSURE
CHANGE

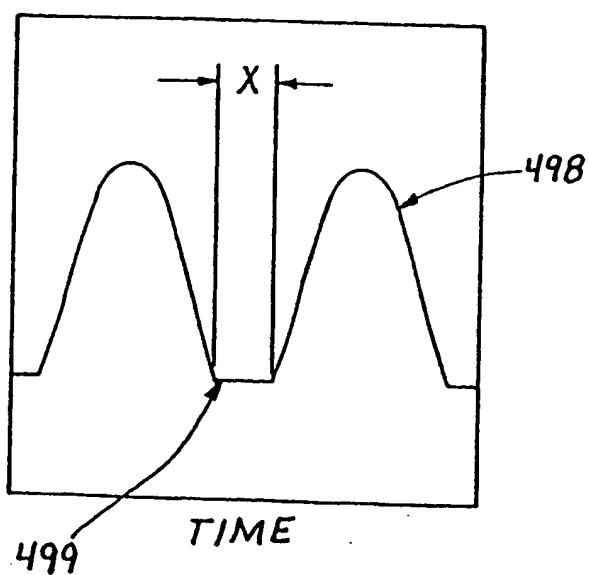
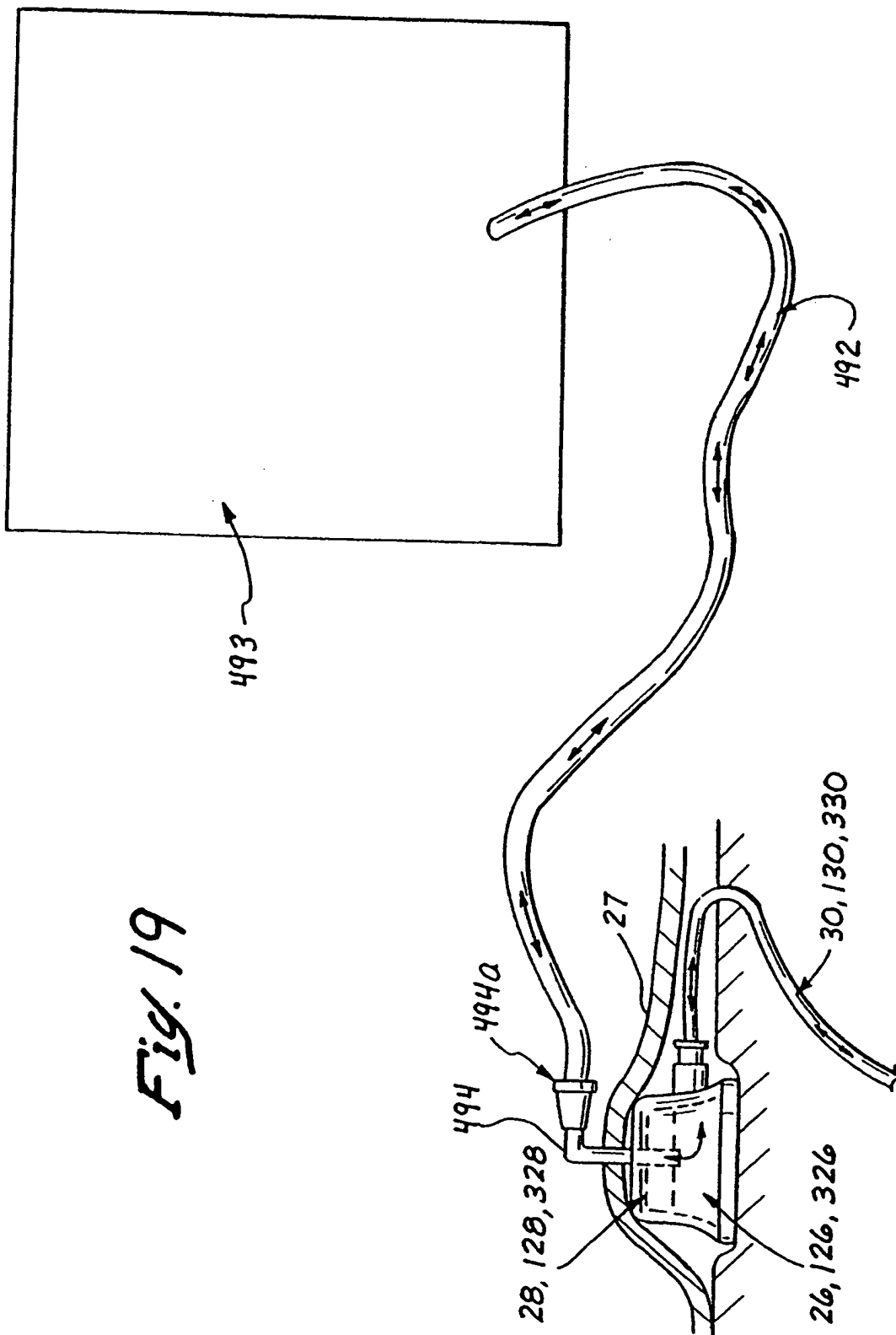


Fig. 18

Fig. 19



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/30138

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M1/10 A61F2/00 A61F2/20 A61B19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 169 381 A (SNYDERS ROBERT V) 8 December 1992 (1992-12-08)	1-4
Y	column 1, line 46-64 column 2, line 16 -column 3, line 26; figure 3	11, 12
Y	US 5 702 343 A (ALFERNES CLIFTON A) 30 December 1997 (1997-12-30) cited in the application column 1, line 54-61 figure 3 column 7, line 16-24	11
Y	WO 98 55165 A (WOODARD JOHN C ; SEARE WILLIAM J JR (US)) 10 December 1998 (1998-12-10) figure 6	12

	-/-	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *&* document member of the same patent family

Date of the actual completion of the international search

2 May 2000

Date of mailing of the international search report

08.08.00

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Bichlmayer, K-P

INTERNATIONAL SEARCH REPORT

Intern al Application No

PCT/US 99/30138

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	figure 3 column 1, line 66 -column 2, line 17 column 2, line 48 -column 3, line 13 column 3, line 40-57 ---	5
A	US 5 749 839 A (KOVACS STEPHEN G) 12 May 1998 (1998-05-12) figures 1,3 column 4, line 23-35 column 5, line 17-40 ---	5-7
A	US 5 197 982 A (GOLDSMITH III MANNING M ET AL) 30 March 1993 (1993-03-30) figures 18-20,25 column 2, line 26-29 column 3, line 4-19 column 4, line 38-41 column 5, line 42-49 ---	8,10
A	US 5 112 303 A (EAST GARY P ET AL) 12 May 1992 (1992-05-12) column 4, line 38 -column 5, line 22 figures 1,3 -----	9

INTERNATIONAL SEARCH REPORT

Int. national application No.
PCT/US 99/30138

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 23-27
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-12

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: 1-12

A device for treating a heart disorder comprising a first structure for placement over a patient's heart and further comprising second and third structures for applying pressure against a first and a second portion of said heart during a portion of the pumping cycle of said heart wherein the pressure applied can be independently controlled.

2. Claims: 13-20

A device for treating a heart disorder comprising a first structure for placement over a patient's heart and further comprising a second structure disposed within said first structure for supporting a portion of said heart and a third structure disposed outside of said first structure to operate in conjunction with the second structure.

3. Claim : 21

A device for treating a heart disorder comprising a containment structure for placement over a patient's heart and further comprising first and second inflation pockets for applying pressure against the heart ventricles and a fluid injection port for independently delivering pressurized fluid to each of said pockets.

4. Claim : 22

A device for treating a heart disorder comprising a containment structure for placement over a patient's heart and further comprising an inflation pocket disposed within said containment structure and a recoil balloon disposed outwardly of said containment structure.

5. Claims: 28-34

A device for treating a heart disorder comprising a containment structure for placement over a patient's heart and further comprising a plurality of inflation pockets for applying pressure against a portion of said heart during at least a portion of the pumping cycle of said heart.

6. Claim : 35

A device for treating a heart disorder comprising a containment structure for placement over a patient's heart and further comprising a drug injection port, a drug delivery line connected to said drug injection port and a plurality of drug flow holes.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

7. Claim : 36

A dual function device for treating a heart disorder comprising a containment structure for placement over a patient's heart and further comprising at least one inflation pocket for applying pressure against a portion of said heart, a fluid injection port and a fluid passage connected between said fluid injection port and said at least one inflation pocket.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern. Application No

PCT/US 99/30138

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